

K090799

**5. 510(K) SUMMARY**

**Submitter:** DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, MA 02767

APR 22 2009

**Contact Person:** Frank Jurczak  
Regulatory Affairs Associate  
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**Date Prepared:** March 23, 2009

**Device Class:** Class III

**Classification Name:** Spinal interlaminar fixation orthosis  
per 21 CFR §888.3050

Spinal intervertebral body fixation orthosis  
per 21 CFR §888.3060

Pedicle screw spinal fixation  
per 21 CFR §888.3070

**Classification Panel:** Orthopedics

**FDA Panel Number:** 87

**Product Code(s):** NKB, KWQ, KWP, MNH, MNI

**Proprietary Name:** EXPEDIUM Spine System

**Predicate Devices:** EXPEDIUM Spine System (K073126)  
EXPEDIUM Spine System (K082195)  
EXPEDIUM Spine System (K041119)  
EXPEDIUM Spine System (K062174)  
Moss Miami Spine System (K955348)  
SFX Snap-Fit Cross Connector (K062196)

**Device Description:** The subject EXPEDIUM Spine System components consist of designs that interface to 5.5mm and 6.35mm rods and are available in various geometries and sizes.

**Intended Use:** The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in

## Special 510(k) Submission – Additions to EXPEDIUM® Spine System

skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

**Materials:** Manufactured from ASTM F 138 implant grade stainless steel.

**Performance Data:** Performance data per ASTM F 1798 were submitted to characterize the subject EXPEDIUM Spine System components addressed in this notification.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DePuy Spine, Inc  
% Mr. Frank Jurczak  
Regulatory Affairs Associate  
325 Paramount Drive  
Raynham, Massachusetts 02767

APR 22 2009

Re: K090799

Trade/Device Name: EXPEDIUM® Spine System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: III  
Product Code: NKB, KWP, KWQ, MNH, MNI  
Dated: March 23, 2009  
Received: March 24, 2009

Dear Mr. Jurczak:

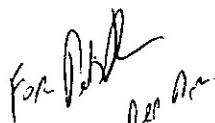
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**4. INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K090799

Device Name: EXPEDIUM® Spine System

Indications For Use:

The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use X \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices**

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**510(k) Number**

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DePuy Spine, Inc., a Johnson & Johnson Company